



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-0575]

Draft Guidance for Industry on Expedited Programs for Serious Conditions--Drugs and
Biologics; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “Expedited Programs for Serious Conditions--Drugs and Biologics.” The purpose of this draft guidance is to provide a single resource for information on FDA’s policies and procedures related to expedited drug development and review programs. The following programs are intended to facilitate and expedite development and review of new drugs to address unmet medical need in the treatment of serious or life-threatening conditions (expedited programs): Fast track designation, breakthrough therapy designation, accelerated approval, and priority review designation.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Submit either electronic or written comments concerning the proposed collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002; or the Office of Communication, Outreach, and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>.

Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Melissa Robb, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6360, Silver Spring MD 20993-0002, 301-796-2500; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Expedited Programs for Serious Conditions--Drugs and Biologics.” This draft guidance provides a single resource for information on FDA’s policies and procedures related to the following expedited programs for serious conditions: (1) Fast track designation, (2) breakthrough therapy designation, (3) accelerated approval, and (4) priority review designation. The draft guidance

describes threshold criteria generally applicable to expedited programs, including what is meant by serious condition, unmet medical need, and available therapy. This draft guidance also discusses considerations for expedited development and review such as manufacturing scale-up and inspections, long-term nonclinical toxicity studies, and review cycle clinical inspections. In addition, this guidance aligns CDER's criteria for priority review designation with CBER's criteria. Only products intended to treat a serious condition are eligible for priority review (unless otherwise eligible under specific statutory provisions).

For over 30 years, expediting the availability of promising therapies to patients with serious conditions has been a priority for FDA. With the passage of the Food and Drug Administration Safety and Innovations Act (FDASIA), FDA is expanding its efforts to expedite development and review of therapies intended to treat patients with serious conditions. This draft guidance is intended to satisfy the statutory requirements of sections 901(c)(1) and 902(b)(1)(A) of FDASIA.

Section 901(c)(1) of FDASIA requires FDA to issue draft guidance to implement amendments to the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (Enhancement of Accelerated Approval Access to New Medical Treatments) within 1 year of the date of enactment. The fast track designation, accelerated approval, and other relevant provisions of this draft guidance are intended to fulfill this requirement.

Section 902(b)(1)(A) of FDASIA requires FDA to issue draft guidance to implement requirements of section 902 (Breakthrough Therapies) within 18 months of the date of enactment. The breakthrough therapy and other relevant provisions of this draft guidance are intended to fulfill this requirement.

The provisions of this draft guidance relating to fast track development and other issues such as serious condition and unmet medical need, when finalized, will replace the current guidance for industry entitled “Fast Track Drug Development Programs--Designation, Development, and Application Review.” The provisions of this draft guidance pertaining to available therapy, when finalized, will replace the current guidance for industry entitled “Available Therapy.”

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency’s current thinking on expedited programs for serious conditions--drugs and biologics. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information that they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register for each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing this notice of the proposed collection of information set forth in this document.

With respect to the collection of information associated with this draft guidance, FDA invites comments on the following topics: (1) Whether the proposed information collected is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimated burden of the proposed information collected, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information collected; and (4) ways to minimize the burden of information collected on the respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Submission of Information Related to Expedited Programs for Serious Conditions-
-Drugs and Biologics

Description of Respondents: Respondents to this collection of information are sponsors that develop drugs and biological products.

Burden Estimate: This draft guidance outlines FDA's policies and procedures related to the following expedited programs for serious conditions: (1) Fast track designation, including rolling review, (2) breakthrough therapy designation, (3) accelerated approval, and (4) priority review designation. In addition, this draft guidance describes threshold criteria generally applicable to expedited programs.

This draft guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR 202.1, parts 314 and 601 (21 CFR parts 314 and 601), and sections 505(a), 506(a)(1), 735, and 736 of the FD&C Act (21 U.S.C. 355(a), 356(a)(1), 379g, and 379h) have been approved under OMB control numbers 0910-0686, 0910-0001, 0910-0338, 0910-0014, and 0910-0297.

This draft guidance proposes the following new collections of information:

Priority Review Designation Request. The draft guidance describes that a sponsor may expressly request priority review of an application. Based on information from FDA's databases and information available to FDA, we estimate that approximately 47 sponsors will prepare and submit approximately 1 priority review designation submission in accordance with the draft guidance and that the added burden for each submission will be approximately 30 hours to develop and submit to FDA as part of the application (totaling 1,410 hours).

Breakthrough Therapy Designation Request. The draft guidance describes the process for sponsors to request breakthrough therapy designation in an application. Based on information available to FDA, we estimate that approximately 24 sponsors will prepare approximately 1 breakthrough therapy designation submission in accordance with the draft guidance and that the added burden for each submission will be approximately 70 hours to prepare and submit (totaling 1,680 hours).

Promotional Materials for Accelerated Approval Under Part 314. The draft guidance describes section 506(c)(2)(B) of the FD&C Act and FDA's accelerated approval regulations (§§ 314.550 and 601.45). These provisions authorize FDA to require sponsors to submit copies of all promotional materials to the Agency for consideration prior to their dissemination. The regulations provide that copies of all promotional materials including promotional labeling as well as advertisements intended for dissemination or publication within 120 days following marketing approval must be submitted to FDA during the preapproval period. The regulations further provide that after 120 days following marketing approval, unless otherwise informed by the Agency, the applicant must submit promotional materials at least 30 days prior to the intended time of initial dissemination of the labeling or initial publication of the advertisement. Currently, FDA has OMB approval for the submission of copies of all promotional materials

under part 601 (OMB control number 0910-0338) but does not have approval for the submission of copies of all promotional materials under part 314.

Based on information from FDA's databases and information available to FDA, we estimate that approximately 20 sponsors will submit promotional materials for accelerated approval 7 times annually in accordance with § 314.550 and that the burden for each submission will be approximately 120 hours (a total of 16,800 hours).

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

Draft Guidance on Expedited Programs	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Priority Review Designation Request	47	1	47	30	1,410
Breakthrough Therapy Designation Request	24	1	24	70	1,680
Promotional Materials for Accelerated Approval Under § 314.550	20	7	140	120	16,800
Total	19,890				

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

III. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either

<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>,

<http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm>, or <http://www.regulations.gov>.

Dated: June 20, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-15250 Filed 06/25/2013 at 8:45 am; Publication Date: 06/26/2013]